1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claim 1,11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 96/39176) in view of Katz (US Patent 4,950,469) and Harley (US 6,641,813). Applicants arguments have been considered and deemed not persuasive.

Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen (see claims 1-13, pages 12-14,40,41). Oral tolerance is a form of “selective immune down regulation” (see specification, page 17, second paragraph). Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see column 6, first paragraph). Katz teaches that agents which prevent binding of said antibodies could be used to treat rheumatic fever (see column 6, first paragraph). Katz teachs that treatment of rheumatic fever would also include use of antibiotics (see column 6, first complete paragraph). Harley establish that the streptococcus to which Katz refers encompasses Streptococcus pyogenes which was known in the art as a species of streptococcus bacteria associated with rheumatic disease (see column 10, first incomplete paragraph). Chen et al. disclose that preparations of whole antigens (aka

intact) can be used (see page 18, last paragraph continued on next page). Any preparation administered to humans would not include live pathogenic bacteria (aka the preparation would be inactivated). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen whilst Katz teaches that teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues wherein the streptococcal antigens would function as an autoantigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Chen et al. teach use of oral tolerance to prevent antibody responses causing autoimmune diseases and Katz disclose that anti streptococcal antibodies are involved in rheumatic fever and that neutralization of said antibodies could be used to treat said disease.

Regarding applicants comment about Katz, Katz teach that rheumatic fever involves ***an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues*** (see column 6, first paragraph). Regarding applicants comments about Chen et al. and the term autoantigen, Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that "*The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals.*".

Regarding applicants comments, the aforementioned sentence indicates that "*The term **also includes** antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals.*", indicating that the term autoantigen also includes the aforementioned antigenic substances.

Regarding applicants unsupported statements that the Chen et al. reference lacks enablement and written description, the MPEP section 716.01(c)II states:

II. < ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

In addition, the MPEP section 2121 states:

2121 [R-6] Prior Art; General Level of Operability Required to Make a Prima

Facie Case
>I. < PRIOR ART IS PRESUMED TO BE OPERABLE/ENABLING
When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

No such evidence has been supplied by applicant. Furthermore, as per Katz, cross reactive bacterial antigens which induce autoimmune antibody responses were already known in the art. In addition, Harley confirms the association of Streptococcus pyogenes and rheumatic disease. Regarding applicants comment about Quinn et al. and streptococcus, Katz et al. teach that rheumatic fever involves ***an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues.*** Harley confirms the association of Streptococcus pyogenes and rheumatic disease. Thus the streptococcal antigen as per disclosed by Katz would **constitute an autoantigen as per the definition of said term in Chen et al**. Regarding applicants comments about Quinn et al. and Gorton et al., Katz et al. teach that rheumatic fever involves ***an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human* tissues** (see **c**olumn 6, first complete paragraph). The streptococcal antigen as per disclosed by Katz would **constitute an autoantigen as per the definition of said term in Chen et al**. In KSR Int'l Co. v. Teleflex Inc ., 550 U.S. __, 2007 WL 1237837, at *13 (2007) it was stated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill".
Regarding applicants comments, Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al.

teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that "*The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals*.".

Regarding applicants comments about Katz, said reference discloses that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see column 6, first paragraph). Katz then discloses that said disease can be treated using an agent that interferes with said antibodies (see column 6, first paragraph). Thus Katz clearly discloses the role of said antigen in rheumatic fever. In addition, Chen et al. disclose that particular antigens can be identified by screening antigens for binding with antibodies from a patient (see page 18, penultimate paragraph).Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues.

Regarding applicants numerous comments about skilled artisans and their opinion on various issues, the MPEP section 716.01(c)II states:

>II. < ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 15 USPQ 716, 718 (CCPA 1965).

3. No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644